

REMARKS

These remarks are filed in response to the non-final Office Action dated April 15, 2008, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

Claims 1-15 are all the claims pending in the current application.

I. Response to Rejection under 35 U.S.C. §103(a)

Claims 1-13 are rejected under 35 U.S.C. § 103 (a) as assertedly being unpatentable over U.S. Patent 6,608,221 (“Toda”) in view of U.S. Patent 6,043,223 (“Black”) or U.S. 2003/0104079 (“Sakanaka”). Particularly, the Examiner’s position is that at the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to prepare an infusion of a known drug (*i.e.*, (2R)-2-propyloctanoic acid) based on the teachings of the prior art on how to prepare infusions.

Applicants traverse and request reconsideration of the rejection in view of the following remarks.

The Examiner asserts the presently claimed invention is obvious based on the combination of teachings of Toda, Black and Sakanaka. However, Applicants respectfully submit that combining the above references is not appropriate in view of technical features and teachings in the disclosure of these references. Furthermore, even if it were appropriate to combine the references, the combination of the references fails to teach all and every element of the presently claimed invention.

According to the Examiner, Toda is characterized to disclose a composition comprising (2R)-2-propyloctanoic acid. However, Toda describes a mixture in a reaction process for *producing* (2R)-2-propyloctanoic acid.

Additionally, per the Examiner, Black describes, on column 5, lines 47-62, an infusion preparation of bradykinin that is dissolved in aqueous solution containing sodium hydroxide and phosphate buffered saline (PBS). However, the above-mentioned part of Black describes that concentration of bradykinin is 15 µg/mL to 50 mg/mL and that 0.09% PBS is used as a carrier when bradykinin is administered intravenously.

According to the Examiner, Sakanaka discloses on page 35 at paragraph [0235] an intravenous infusion where the active compound is dissolved in an aqueous solution containing sodium chloride, phosphate buffer, glucose, liposome or fat emulsion. Sakanaka describes that dihydrogensenoside Rb₁ is administered intravenously after dissolution into physiological saline, distilled water, phosphate buffer, glucose solution, liposome or fat emulsion.

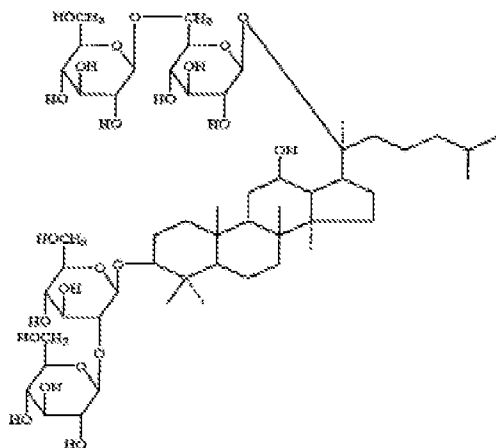
The Examiner combines Toda, Black and Sakanaka to reject the subject matter defined the claims of the instant application.

The presently claimed invention is directed to an infusion preparation comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion. Dependent claims further define the amount and kinds of the ingredients in the infusion. Such infusion is free from clouding, which could be caused by the fluctuation of pH of the infusion.

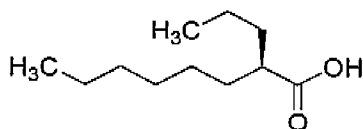
Applicants submit that even if Toda discloses the compound (2R)-2-propyloctanoic acid, the combination of Black and Sakanaka with Toda still does render the presently claimed invention obvious. Bradykinin, of which infusion preparation is disclosed by Black, is a basic

peptide consisting of nine amino acids. It has structure of H-Arg-Pro-Pro-Gly-Phe-Ser-Pro-Phe-Arg-OH and molecular weight thereof is about 1,060.

Dihydroginsenoside Rb₁ of which intravenous infusion is disclosed by Sakanaka has the following structure (paragraph [0230]):



The dihydroginsenoside Rb₁ is a neutral compound having molecular weight of about 1,111. On the contrary, as described in the specification of the present application, (2R)-2-propyloctanoic acid has the following structure:



(2R)-2-propyloctanoic acid is an acidic compound having molecular weight of about 186. Thus, even if (2R)-2propyloctanoic acid is a known compound, a person skilled in the art would have not expect an infusion preparation in the present application based on combination of a composition for intravenous administration of giant molecules which are not acidic molecules such as those disclosed in Black and Sakanaka.

Furthermore, a person skilled in the art would not have been motivated to combine molecules which each are known to have different physicochemical properties.

Additionally, because both Black and Sakanaka are directed to a method for intravenous administration of neutral or basic compounds having molecular weight of 1,000 or more, one skilled in the art would not have been motivated to combine the teachings of Black and Sakanaka with the teaching of Toda with a reasonable expectation of success or predictability to reach the subject matter defined in the claims.

Accordingly, the rejection is not sustainable and Applicants respectfully request that the rejection be withdrawn.

II. Response to Double Patenting Rejection

Claims 1-13 are *provisionally* rejected on the ground of non-statutory obviousness-type double patenting as being assertedly unpatentable over claims 1-5, and 7-13 of co-pending Application No. 10/574,477.

Applicants respectfully request that the rejection be withdrawn in view of Applicants' submission of a Terminal Disclaimer, concurrently filed herewith.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565

CUSTOMER NUMBER

Date: October 15, 2008

Sunhee Lee
Registration No. 53,892